

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 22-0113V

SUZANNE KALLIN,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: November 12, 2024

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for Petitioner.

Jamica Marie Littles, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On February 3, 2022, Suzanne Kallin filed a Petition under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”); see Section 11(c)(1)(D)(i). Petitioner alleges a right shoulder injury related to vaccine administration (“SIRVA”) following her receipt of an influenza (“flu”) vaccine in her right arm on September 9, 2020. The case was assigned to the Special Processing Unit (“SPU”) of the Office of Special Masters.

Based on review of the evidence, I hereby determine that Petitioner’s right shoulder pain likely began within 48 hours of vaccination (notwithstanding a treatment

¹ Because this ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims’ website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

delay). Thus, given the lack of any other objections from Respondent, Petitioner has preponderantly established all other requirements for a Table SIRVA claim – making her entitled to compensation.

I. Procedural History

The case was assigned to the SPU in April 2022. After Respondent completed his review of the evidence, the parties engaged in settlement discussions, but which ultimately reached an impasse in March 2024. Accordingly, on May 14, 2024, Respondent filed his Rule 4(c) Report arguing that Petitioner was not entitled to compensation because “she could not demonstrate 48-hour post-vaccination pain onset. Rule 4(c) Report (ECF No. 37) at 5. Petitioner’s supplemental affidavit, Ex. 10, was followed by briefing. Brief filed July 22, 2024 (ECF No. 42); Response filed Sept. 11, 2024 (ECF No. 43); Reply filed Sept. 26, 2024 (ECF No. 44). The matter is ripe for adjudication.

II. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner’s injury or illness that is contained in a medical record. Section 13(b)(1). “Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.” *Cucuras v. Sec’y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec’y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. “Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.” *Murphy v. Sec’y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff’d per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). And the Federal Circuit recently “reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient’s physical conditions.” *Kirby v. Sec’y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id.*

A special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,³ a petitioner must

³ In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. See Section 11(c)(1)(A)(B)(D)(E).

establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

III. Finding of Fact

I make the following onset finding after a complete review of the record (all medical records, affidavits, Respondent's Rule 4 report, and additional evidence and briefs filed), and highlight the following facts:

- Petitioner was born in 1968 (and was thus nearly 52 years old at the time of vaccination). She was an established patient of Kaiser Permanente, where she worked as perfusionist,⁴ and her husband worked as a cardiac surgeon. Ex. 2 at 147.
- Petitioner sometimes asked her husband physician for medical advice before obtaining a more formal and relevant evaluation. For instance, in 2018 a dermatologist recorded that Petitioner had a "lip cut no injury 6 months... never went away. Patient husband... told her she will need to be evaluated." Ex. 2 at 112. A biopsy of the lip sore identified basal cell carcinoma, prompting two Mohs surgeries. *Id.* at 136 – 37, 173, 196 – 97, 318 – 19.
- In contrast in December 2019, Petitioner sought emergency attention promptly after sustaining a left knee injury – assessed as an ACL tear – in a skiing accident. Ex. 5 at 6 – 23; Ex. 2 at 539 – 42, 560 – 63. She had no history of left shoulder pain or dysfunction, however. *See generally* Ex. 2.
- The at-issue flu vaccine was administered to Petitioner's left deltoid on September 10, 2020, at approximately 2:00 p.m. Ex. 2 at 604 – 05; Ex. 3 at 8 – 9. The vaccination occurred at Kaiser Permanente. *Id.* Petitioner left work at 3:52 p.m. (approximately two hours earlier than scheduled). Ex. 9 at 3.
- More than a month later, on October 19, 2020, Petitioner obtained a "self-request... same-day" bilateral mammogram screening. The record does not address the presence or absence of left shoulder pain. Ex. 6 at 12 – 13. And there are no intervening medical records between this occurrence and the vaccination date.

⁴ A perfusionist is a medical professional who operates a heart-lung machine that "artificially replaces a patient's heart or lung functions during surgery." UT Health Houston – McGovern Medical School Cardiovascular Perfusion Program, *What is a Perfusionist?*, <https://med.uth.edu/perfusion/about-us/what-is-a-perfusionist/#:~:text=Perfusionists%20are%20vital%20members%20of,or%20lung%20functions%20during%20surgery>. (last visited Nov. 7, 2024), cited in Response at n. 2.

- The next record is from four months and eleven (11) days post-vaccination, on January 21, 2021, when Petitioner underwent an MRI of the left shoulder at a Kaiser Permanente facility. Ex. 6 at 18. The MRI was ordered by a Kaiser Permanente orthopedist, Nima Mehran, M.D., without any preceding evaluation or recorded communication with Petitioner. *Id.*⁵ The MRI report's clinical history section reads: "Left sh pain. Evaluate cuff and cartilage [sic]. Possible adhesive capsulitis as well." *Id.* at 19. The findings included adhesive capsulitis, a possible labral tear, minimal fluid in the subacromial/ subdeltoid bursa, and minimal degenerative arthrosis in the acromioclavicular joint. *Id.*
- During a February 3, 2021, telephone appointment (lasting a total of 13 minutes), the orthopedist did not record any history of present illness ("HPI") from Petitioner – apart from her apparent use of Gabapentin 100 mg tablets.⁶ Ex. 2 at 612 – 13. And the telephone encounter obviously did not involve any visual observation or physical examination. *Id.* The orthopedist "discussed MRI results and frozen shoulder. Reviewed pathology and natural history with both [Petitioner] and her husband who is a cardiothoracic surgeon at LAMC... She will try to work on exercises we discussed and work with physical therapy ["PT"]. If pain gets worse, she will reach out for a CSI. At which point I will ref[er] to [Kaiser Permanente sports medicine specialist Michael Kaho Fong, M.D.] for US injection." *Id.* at 612. Approximately thirty (30) minutes after that telephone call, Petitioner confirmed that she did want to schedule the steroid injection. *Id.* at 619.
- At their February 9, 2021 encounter, the sports medicine specialist recorded Petitioner's chief complaint as: "Left shoulder pain[.] Insidious onset[.] ? After influenza vaccine[.] Decreasing ROM [range of motion] of left shoulder[.]" Ex. 2 at 624. A physical exam confirmed decreased ROM, the assessment remained adhesive capsulitis, and a corticosteroid injection was administered to the left glenohumeral joint. *Id.* at 625. The physician also offered home exercises, echoed the referral to formal PT, and cautioned that Petitioner "may require 1 year of aggressive PT to gain full ROM." *Id.*

⁵ Certified medical records dating from three years prior to vaccination do not reflect any prior treatment with the orthopedist. See *generally* Exs. 2, 4, 6; see also Ex. 10 at ¶ 1 (Petitioner's confirmation of no prior treatment); *id.* at ¶ 3 (explaining that in early 2021, she called Dr. Mehran, who decided "from [Petitioner's] description of [her] shoulder, and with the difficulties of getting an appointment, that he would just order the MRI and we would talk about it after he got the results").

⁶ The gabapentin was apparently prescribed for an acute unrelated medical issue over a year earlier, see Ex. 2 at 424, but the subsequent reference suggests that Petitioner may have taken the leftover tablets to help manage her shoulder pain prior to seeking formal medical treatment for that concern.

- During a February 16, 2021, telehealth video consult, a physical therapist recorded that Petitioner had experienced “pain left shoulder since 9/2020, ROM decreased... began as a result of the flu shot.” Ex. 2 at 651. The pain rated 0/10 at rest and 5/10 with activity. *Id.* The therapist recorded objective findings of reduced ROM, an assessment of frozen shoulder, and recommendations of a home exercise program, ice, heat, and rest. *Id.* at 652. Petitioner was instructed to follow up as needed – but after six weeks of no follow up, she was administratively discharged from PT. *Id.* at 649.
- Next, at a June 4, 2021, initial evaluation with a different physical therapist (still within Kaiser Permanente), Petitioner reported that her left shoulder pain onset was in September 2020, beginning “after getting the flu shot.” Ex. 4 at 39. She attended a total of four formal PT sessions, which included instruction on home exercises. *Id.* at 39 – 41, 57 – 59, 90 – 91, 116 – 18. At the last session on July 27, 2021, Petitioner reported that her ROM had “improved significantly” and her pain rating was 0/10. *Id.* at 116. She opted to discontinue formal PT, and the therapist concurred that she would likely achieve all remaining goals with a HEP. *Id.* at 117. There are no other relevant medical records.
- Petitioner recalls that her September 10, 2020, vaccination was “extremely painful.” Ex. 8 at ¶ 2. Afterwards, she experienced ongoing left shoulder pain, complained to coworkers, had difficulty resuming her work duties, and received her supervisor’s approval to leave more than three years before the end of her shift. *Id.*; see also Ex. 9 at 3 (time sheet corroborating this allegation). Over the following weeks her shoulder pain persisted, and her ROM began to decrease, but she had difficulty obtaining a primary care evaluation due to the COVID Pandemic. Ex. 8 at ¶ 3. Eventually she called the aforementioned orthopedist, who facilitated an MRI and telehealth consult. *Id.* at ¶ 4; see also Ex. 10 at ¶¶ 2 – 5 (maintaining that her shoulder pain began “immediately” upon vaccination, but she “thought [she] was being a team player by neglecting [her] own medical care for people with truly emergent medical issues” during the Pandemic).
- Petitioner’s husband has confirmed that she “told [him] on the evening of September 10, 2020, that her flu shot administration was very painful and that she continued to have pain.” Ex. 9 at 1.

- Similarly, a coworker recalls that “[a]fter her flu shot, [Petitioner] was complaining that her flu shot was painful, and her arm hurt. She left early that day. Her shift ended at 7 pm and her timecard shows she left at 3:52 pm.” Ex. 9 at 2.⁷

The only issue in dispute is whether or not Petitioner’s left shoulder pain began within forty-eight (48) hours post-vaccination, as required for a Table SIRVA claim. 42 C.F.R. §§ 100.3(a), (c)(10)(ii). Respondent argues that the injury’s onset is *unknown* – based on the *absence* of any objective medical records documenting a left shoulder injury for over four months post-vaccination. Response at 7 – 8. But the Act explicitly rules out obligating petitioners to prove onset *based* on evidence created close-in-time to the alleged onset. Section 13(b)(2) (permitting a finding of onset within the Table timeframe, even if “the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period”).

The subsequent records are somewhat lacking in detail, or vague, about when the shoulder injury began. But Petitioner has explained that the medical evaluations obtained were somewhat informal (from colleagues within her health system or her own physician husband). And special masters reasonably understand terms like “since” or “after” to mean *very close in time* – and hence are commonly construed to mean occurring within 48 hours after the referenced inciting event.⁸ Respondent otherwise has not pointed to any evidence suggesting that Petitioner’s left shoulder was symptom-free during the initial treatment delay, or that it was injured at some other point *beyond* 48 hours post-vaccination.

Respondent further notes that notwithstanding the Pandemic, Petitioner had options for accessing medical care – including telemedicine. Response at 7 – 8. But Petitioner has credibly explained that her shoulder injury progressed over time – and she had previously consulted her physician husband before seeking formal treatment for other medical concerns (e.g., a skin abnormality that proved to be cancerous). Petitioner’s conduct is less relevant to the fact of onset, and instead more relevant to an assessment of the degree of her pain and suffering during the same time period (and certainly a case featuring limited treatment and long treatment gaps will not result in a significant pain and suffering award).

⁷ Respondent also argues that Petitioner’s husband and coworker offered unsworn statements. Response at 4. But both are “signed under the pains and penalties of perjury.” See 28 U.S.C.A. § 1746 (providing that such a declaration may be afforded like force and effect as a notarized affidavit). I thus consider them to have some evidentiary trustworthiness, even if they do not precisely fit the requirements of a federal declaration.

⁸ Petitioner’s Reply at 2 – 3 and n. 6 cites numerous such cases.

Moreover, Petitioner's onset allegation is corroborated by a timecard reflecting her early departure from work (after receiving the vaccination at her place of employment), as well as by her husband and coworker's firsthand observations. The coworker's declaration is particularly relevant, given that he has no apparent "interest in the outcome" of this litigation. *Compare* Response at 10, citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611 (Fed. Cl. Spec. Mstr. June 30, 1998) (concerning the recollections of parents pursuing a claim on behalf of their child).

Accordingly, I find there is preponderant evidence to establish that onset of Petitioner's pain occurred within 48 hours of vaccination.

Conclusion and Scheduling Order

Respondent does not raise any other objections to entitlement, see Response at n. 6 (confirming that he "solely contests the QAI requirement of onset"), and based on my independent review, I find that Petitioner has preponderantly established all other requirements for a Table SIRVA claim. 42 C.F.R. §§ 100.3(a), (c)(10). Accordingly, she need not prove causation-in-fact. Section 11(c)(1)(C). I also find that Petitioner has satisfied all other requirements of Section 11(c) including a sufficiently severe injury, and the lack of other award or settlement. Section 11(c)(A), (B), and (D).

For the foregoing reasons, **I find that Petitioner has established entitlement and is thus entitled to compensation for a SIRVA following her September 10, 2020, flu vaccine.** Therefore, the case is now formally in the damages phase.

By no later than Thursday, December 12, 2024, Petitioner shall file a Status Report updating on the parties' efforts towards informally resolving damages.⁹

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master

⁹ In November 2022, Petitioner reported that the claim did not involve a Medicaid lien or ongoing treatment, and she conveyed a pain and suffering demand to Respondent. See Status Reports (ECF Nos. 22, 24). The parties subsequently engaged in settlement discussions from June 2023 – March 2024. Thus, it is expected that the parties can promptly determine whether damages can be informally resolved, and if not, jointly propose a reasonable schedule for briefing their respective positions as to the appropriate award for Petitioner's past pain and suffering.